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PTO/SB/21 (09-04)

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

7+

Application Number

10/630,074

Filing Date

07/30/2003

First Named Inventor

David R. Milich

Art Unit

1648

Examiner Name

Peng, B.

Attorney Docket Number

VACCINE-07971

ENCLOSURES (Check all that apply)

| | | |
|---|---|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form | <input type="checkbox"/> Drawing(s) | <input type="checkbox"/> After Allowance Communication to TC |
| <input checked="" type="checkbox"/> Fee Attached | <input type="checkbox"/> Licensing-related Papers | <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences |
| <input type="checkbox"/> Amendment/Reply | <input type="checkbox"/> Petition | <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) |
| <input type="checkbox"/> After Final | <input type="checkbox"/> Petition to Convert to a Provisional Application | <input type="checkbox"/> Proprietary Information |
| <input type="checkbox"/> Affidavits/declaration(s) | <input type="checkbox"/> Power of Attorney, Revocation | <input type="checkbox"/> Status Letter |
| <input type="checkbox"/> Extension of Time Request | <input type="checkbox"/> Change of Correspondence Address | <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): |
| <input type="checkbox"/> Express Abandonment Request | <input type="checkbox"/> Terminal Disclaimer | Form PTO-1449 & copies of 28 references cited therein |
| <input checked="" type="checkbox"/> Information Disclosure Statement | <input type="checkbox"/> Request for Refund | |
| <input type="checkbox"/> Certified Copy of Priority Document(s) | <input type="checkbox"/> CD, Number of CD(s) _____ | |
| <input type="checkbox"/> Reply to Missing Parts/Incomplete Application | <input type="checkbox"/> Landscape Table on CD | |
| <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 | | |

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | | | |
|--------------|-----------------------------|----------|--------|
| Firm Name | Medlen & Carroll, LLP | | |
| Signature | <i>Christine A. Lekutis</i> | | |
| Printed name | Christine A. Lekutis | | |
| Date | May 10, 2006 | Reg. No. | 51,934 |

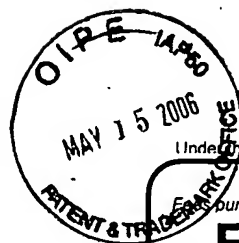
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| Signature | <i>Cliff Cannon</i> | | |
| Typed or printed name | Cliff Cannon-Cin | Date | May 10, 2006 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO/SB/17 (12-04v2)

Approved for use through 07/31/2006, OMB 0651-0032

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Effective on 12/08/2004.

Pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL

For FY 2005

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 180.00

Complete if Known

| | |
|----------------------|-----------------|
| Application Number | 10/630,074 |
| Filing Date | 07/30/2003 |
| First Named Inventor | David R. Milich |
| Examiner Name | Peng, B. |
| Art Unit | 1648 |
| Attorney Docket No. | VACCINE-07971 |

METHOD OF PAYMENT (check all that apply)☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____☒ Deposit Account Deposit Account Number: 08-1290 Deposit Account Name: Medlen & Carroll, LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below☐ Charge fee(s) indicated below, except for the filing fee☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

| Application Type | FILING FEES | | SEARCH FEES | | EXAMINATION FEES | | Fees Paid (\$) |
|------------------|-------------|-----------------------|-------------|-----------------------|------------------|-----------------------|----------------|
| | Fee (\$) | Small Entity Fee (\$) | Fee (\$) | Small Entity Fee (\$) | Fee (\$) | Small Entity Fee (\$) | |
| Utility | 300 | 150 | 500 | 250 | 200 | 100 | |
| Design | 200 | 100 | 100 | 50 | 130 | 65 | |
| Plant | 200 | 100 | 300 | 150 | 160 | 80 | |
| Reissue | 300 | 150 | 500 | 250 | 600 | 300 | |
| Provisional | 200 | 100 | 0 | 0 | 0 | 0 | |

2. EXCESS CLAIM FEES**Fee Description**

Each claim over 20 (including Reissues)

| Fee (\$) | Small Entity Fee (\$) |
|----------|-----------------------|
| 50 | 25 |

Each independent claim over 3 (including Reissues)

| | |
|-----|-----|
| 200 | 100 |
|-----|-----|

Multiple dependent claims

| | |
|-----|-----|
| 360 | 180 |
|-----|-----|

| Total Claims | Extra Claims | Fee (\$) | Fee Paid (\$) |
|--------------|----------------|----------|---------------|
| 61 | - 20 or HP = 0 | x | = |

HP = highest number of total claims paid for, if greater than 20.

| Indep. Claims | Extra Claims | Fee (\$) | Fee Paid (\$) |
|---------------|---------------|----------|---------------|
| 4 | - 3 or HP = 0 | x | = |

HP = highest number of independent claims paid for, if greater than 3.

| Multiple Dependent Claims | Fee (\$) | Fee Paid (\$) |
|---------------------------|----------|---------------|
| | | |

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof | Fee (\$) | Fee Paid (\$) |
|--------------|--------------|--|--------------------------------|---------------|
| | - 100 = | / 50 = | (round up to a whole number) x | = |

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Fees Paid (\$)

Other (e.g., late filing surcharge): Information Disclosure Statement fee

180

SUBMITTED BY

| | | | |
|-------------------|----------------------|--|------------------------|
| Signature | | Registration No. (Attorney/Agent) 51,934 | Telephone 415.904.6500 |
| Name (Print/Type) | Christine A. Lekutis | | Date May 10, 2006 |

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: David R. Milich *et al.*

Serial No.: 10/630,074

Group No.: 1648

Filed: 07/30/2003

Examiner: Peng, B.

Entitled: **Human Hepatitis B Virus Core Proteins As Vaccine Platforms
And Methods Of Use Thereof**

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

MS Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on May 10, 2006.

By: _____

Cliff Cannon-Cin

Dear Sir:

The citations listed below, copies of non-U.S. patents and published applications attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. § 1.56 and § 1.97. The Examiner is requested to make these citations of official record in this application:

- U.S. Patent No. 5,990,085 to Ireland *et al.*, "Inhibin-HBc fusion protein," (1999);
- U.S. Patent No. 6,887,464 to Coleman *et al.*, "Advanced antigen presentation platform," (2005);
- U.S. Publication No. US 2003/0099668 of Bachmann *et al.*, "Packaging of immunostimulatory substances into virus-like particles: method of preparation and use," (2003);
- U.S. Publication No. US 2004/0054139 of Page *et al.*, "Modification of hepatitis B core

05/16/2006 SSANDARA 00000018 10630074
antigen," (2004);

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01 FC:1806

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- U.S. Publication No. US 2004/0146524 of Lyons *et al.*, "Stabilized immunogenic HBc chimer particles," (2004);
- U.S. Publication No. US 2004/0152876 of Birkett, "Immunogenic HBc chimer particles having enhanced stability," (2004);
- U.S. Publication No. US 2004/0156864 of Birkett, "Immunogenic HBc chimer particles having enhanced stability," (2004);
- U.S. Publication No. US 20040219164 of Coleman *et al.*, "Advanced antigen presentation platform," (2004);
- U.S. Publication No. US 2005/0208068 of Milich *et al.*, "Malaria immunogen and vaccine," (2005);
- Japanese Patent Application Publication No. JP7252300 of Okamoto "Antigen fused protein from duck hepatitis virus and human hepatitis virus and its production," (1995) in Japanese with English translation of abstract and specification;
- PCT Publication No. WO 95/27083 of Milich *et al.*, "Method for diagnosing chronic hepatitis B virus infection," (1995);
- PCT Publication No. WO 99/40934 of Birkett, "Strategically modified hepatitis B core proteins and their derivatives," (1999);
- PCT Publication No. WO 00/46365 of Coleman *et al.*, "Advanced antigen presentation platform," (2000);
- Belnap *et al.*, "Diversity of core antigen epitopes of hepatitis B virus," Proc Natl Acad Sci USA, 100:10884-10889 (2003);
- Fietelson *et al.*, "Core particles of hepatitis B virus and ground squirrel hepatitis virus," J Virol, 43:687-696 (1982);
- Fietelson *et al.*, "Monoclonal antibodies raised to purified woodchuck hepatitis virus core antigen particles demonstrate X antigen reactivity," Virology, 177:357-366 (1990);
- Galibert *et al.*, "Nucleotide sequence of a cloned woodchuck hepatitis virus genome: Comparison with the hepatitis B virus sequence," J Virol, 41:51-65 (1982);
- Gallina *et al.*, "A recombinant hepatitis B core antigen polypeptide with the protamine-like domain deleted self-assembles into capsid particles but fails to bind nucleic acids," J Virol, 63:4645-4652 (1989);

- Kidd-Ljunggren *et al.*, "Genetic variability in hepatitis B viruses," J Gen Virol, 83:1267-1280 (2002);
- Koschel *et al.*, "Extensive mutagenesis of the hepatitis B virus core gene and mapping of mutations that allow capsid formation," J Virol, 73:2153-2160 (1999);
- Marion *et al.*, "A virus in Beechey ground squirrels that is related to hepatitis B virus of humans," Proc Natl Acad Sci USA, 77:241-2945 (1980);
- Mason *et al.*, "Virus of Pekin ducks with structural and biological relatedness to human hepatitis B virus," J Virol, 36:829-836 (1980);
- Milich *et al.*, "Immune response to hepatitis B virus core antigen (HBcAg): Localization of T cell recognition site within HBcAg/HBeAg," J Immunol, 139:1223-1231 (1987);
- Milich *et al.*, "Antibody production to the nucleocapsid and envelope of the hepatitis B virus primed by a single synthetic T cell site," Nature, 329:547-549 (1987);
- Milich *et al.*, "Comparative immunogenicity of hepatitis B virus core and E antigens" J Immunol, 141:3617-3624 (1988);
- Millman *et al.*, "Immunological Cross-reactivities of woodchuck and hepatitis B viral antigens," Infect Immun, 35:752-757 (1982);
- Ponzetto *et al.*, "Core antigen and antibody in woodchucks after infection with woodchuck hepatitis virus," J Virol, 52:70-76 (1984);
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- Tarar *et al.*, "Expression of a human cytomegalovirus gp58 antigenic domain fused to the hepatitis B virus nucleocapsid protein," FEMS Immunol Med Microbiol, 16:183-192 (1996);
- Ulrich *et al.*, "Core particles of hepatitis B virus as carrier for foreign epitopes," Advances in Virus Research, 50:141-182 (1998);
- Werner *et al.*, "Serological relationship of woodchuck hepatitis virus to human hepatitis B virus," J Virol, 32:314-322 (1979);
- Zheng *et al.*, "The structure of hepadnaviral core antigens," J Biol Chem, 267:9422-9429 (1992); and
- Zlotnick *et al.*, "Localization of the C terminus of the assembly domain of hepatitis B virus capsid protein: Implications for morphogenesis and organization of encapsidated RNA," Proc Natl Acad Sci USA, 94:9556-9561 (1997).

This Information Disclosure Statement under 37 C.F.R. § 1.56 and § 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: May 10, 2006



Christine A. Lekutis
Registration No. 51,934

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San Francisco, California 94105
415/904-6500

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|---|--|--|--|--|------------------------|
| FORM PTO-1449 (Modified) | | U.S. Department of Commerce Patent and Trademark Office | | Attorney Docket No.: VAGCINE-07971 | Serial No.: 10/630,074 |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary) | | | | Applicant: David R. Milich <i>et al.</i> | |
| (37 CFR § 1.98(b)) | | | | Filing or 371(c) Date: 07/30/2003 | Group Art Unit: 1648 |

| U.S. PATENT DOCUMENTS | | | | | | | |
|-----------------------|----------|------------------------|------------|------------------------|-------|----------|-------------|
| Examiner Initials | Cite No. | Serial / Patent Number | Issue Date | Applicant / Patentee | Class | Subclass | Filing Date |
| | 1 | 5,990,085 | 11/23/1999 | Ireland <i>et al.</i> | | | |
| | 2 | 6,887,464 | 05/03/2005 | Coleman <i>et al.</i> | | | |
| | 3 | 2003/0099668 | 05/29/2003 | Bachmann <i>et al.</i> | | | |
| | 4 | 2004/0054139 | 03/18/2004 | Page <i>et al.</i> | | | |
| | 5 | 2004/0146524 | 07/29/2004 | Lyons <i>et al.</i> | | | |
| | 6 | 2004/0152876 | 08/05/2004 | Birkett | | | |
| | 7 | 2004/0156864 | 08/12/2004 | Birkett | | | |
| | 8 | 2004/0219164 | 11/04/2004 | Coleman <i>et al.</i> | | | |

| FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS | | | | | | | | |
|--|----|-----------------|------------------|-------------------------|-------|----------|-------------|----|
| | | Document Number | Publication Date | Country / Patent Office | Class | Subclass | Translation | |
| | | | | | | | Yes | No |
| | 9 | JP7252300 | 10/03/1995 | Japan | | | X | |
| | 10 | WO 95/27083 | 10/12/1995 | WIPO | | | | |
| | 11 | WO 99/40934 | 08/19/1999 | WIPO | | | | |
| | 12 | WO 00/46365 | 08/10/2000 | WIPO | | | | |

| OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication) | | |
|---|----|--|
| | 13 | Belnap <i>et al.</i> , "Diversity of core antigen epitopes of hepatitis B virus," Proc Natl Acad Sci USA, 100:10884-10889 (2003) |
| | 14 | Fietelson <i>et al.</i> , "Core particles of hepatitis B virus and ground squirrel hepatitis virus," J Virol, 43:687-696 (1982) |
| | 15 | Fietelson <i>et al.</i> , "Monoclonal antibodies raised to purified woodchuck hepatitis virus core antigen particles demonstrate X antigen reactivity," Virology, 177:357-366 (1990) |
| | 16 | Galibert <i>et al.</i> , "Nucleotide sequence of a cloned woodchuck hepatitis virus genome: Comparison with the hepatitis B virus sequence," J Virol, 41:51-65 (1982) |
| | 17 | Gallina <i>et al.</i> , "A recombinant hepatitis B core antigen polypeptide with the protamine-like domain deleted self-assembles into capsid particles but fails to bind nucleic acids," J Virol, 63:4645-4652 (1989) |
| | 18 | Kidd-Ljunggren <i>et al.</i> , "Genetic variability in hepatitis B viruses," J Gen Virol, 83:1267-1280 (2002) |
| | 19 | Koschel <i>et al.</i> , "Extensive mutagenesis of the hepatitis B virus core gene and mapping of mutations that allow capsid formation," J Virol, 73:2153-2160 (1999) |
| | 20 | Marion <i>et al.</i> , "A virus in Beechey ground squirrels that is related to hepatitis B virus of humans," Proc Natl Acad Sci USA, 77:241-2945 (1980) |
| | 21 | Mason <i>et al.</i> , "Virus of Pekin ducks with structural and biological relatedness to human hepatitis B virus," J Virol, 36:829-836 (1980) |
| | 22 | Milich <i>et al.</i> , "Immune response to hepatitis B virus core antigen (HBcAg): Localization of T cell recognition site within HBcAg/HBeAg," J Immunol, 139:1223-1231 (1987) |
| | 23 | Milich <i>et al.</i> , "Antibody production to the nucleocapsid and envelope of the hepatitis B virus primed by a single synthetic T cell site," Nature, 329:547-549 (1987) |
| | 24 | Milich <i>et al.</i> , "Comparative immunogenicity of hepatitis B virus core and E antigens" J Immunol, 141:3617-3624 (1988) |
| | 25 | Millman <i>et al.</i> , "Immunological Cross-reactivities of woodchuck and hepatitis B viral antigens," Infect Immun, 35:752-757 (1982) |

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| Examiner: | Date Considered: |
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| EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |
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